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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,118	11/13/2003	Toshiyuki Takai	671302-2002	8301
20999 7590 04/23/2007 FROMMER LAWRENCE & HAUG 745 FIFTH AVENUE- 10TH FL. NEW YORK, NY 10151			EXAMINER IIAMA, JOANNE	
			ART UNIT	PAPER NUMBER
			1632	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		04/23/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/712,118	<b>Applicant(s)</b> TAKAI ET AL.	
	<b>Examiner</b> Joanne Hama, Ph.D.	<b>Art Unit</b> 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 January 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3-5,19 and 20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-5,19 and 20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Applicant filed a response to the Office Action of October 11, 2006 on January 9, 2007. Claims 2, 6-18 are cancelled. Claims 3-5 are amended.

Claims 1, 3-5, 19, 20 are under consideration.

### ***Information Disclosure Statement***

Applicant filed Information Disclosure Statements (IDSes) on January 9, 2007 and February 22, 2007. The IDSes have been considered.

### **Maintained Rejection**

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-5, 19, 20 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for

a transgenic mouse comprising a homozygous disruption of DAP12 (DNAX Activation Protein 12) in its genome, wherein the transgenic mouse exhibits hypomyelinos of the thalamus, and wherein the mouse exhibits Nasu-Hakola disease, does not reasonably provide enablement for

a transgenic mouse comprising a homozygous disruption of DAP12 (DNAX Activation Protein 12) in its genome wherein the transgenic mouse exhibits

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hypomyelinos of the thalamus, and wherein the mouse exhibits neuropsychiatric disorders associated with disruption in DAP12 gene function.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims for reasons of record, October 11, 2006, June 16, 2006, and December 30, 2005.

Applicant's arguments filed January 9, 2007, pages 4-7, have been fully considered but they are not persuasive.

Applicant indicates that claims 3-5 have been amended to recite that the disorders are "associated with disruption in DAP12 gene function." As such, one skilled in the art is enabled to practice the invention as disclosed in the instant claims without undue experimentation (Applicant's response, page 6, 1<sup>st</sup> parag.). In response, the amendment is not persuasive because while the specification teaches that the claimed mouse is a model of Nasu-Hakola disease and that the mouse exhibits an impairment in sensorimotor gaiting, which is characteristic of neuropsychiatric disorders including dementia, schizophrenia, schizotypal personality disorders, obsessive compulsive disorders, and Tourette's syndrome (specification, page 19), the specification does not teach that the neuropsychiatric disorders result independent of the Nasu-Hakola disease. Rather, the Nasu-Hakola disease (characterized by CNS hypomyelinos) results in the exhibition of the symptoms, which include dementia and schizophrenia. As such, the amendment is not persuasive and the rejection as it applies to this issue remains.

With regard to the publication of Schmitt et al., 2004, Applicant indicates that Schmitt et al. mentions decreased myelination of neurons in the thalamus of schizophrenic patients. The Office Action cites references that refer to dementia associated with tau mutations and Parkinson's disease, but the instant claims disclose dementia associated with disruption in DAP12 gene function (Applicant's response, page 6, 4<sup>th</sup> parag.). In response, while Applicant provides Schmitt et al., it is not entirely clear what about Schmitt et al. that provide support for Applicant's claims. Did Applicant intend to mean that because Schmitt et al. indicate that because there is a certain pathology (i.e. decrease in myelination) exhibited by patients that the pathology is only caused by DAP12 disruption and is distinct from the pathology seen in dementia of other diseases such as Parkinson's disease? In response, this is not persuasive because pathology is not indicative of etiology. Note for example, that the art teaches that other neurological disease exhibit hypomyelination (e.g. multiple sclerosis, metachromatic leukodystrophy, Corfas et al., 2004, Nature Neuroscience, 7: 575-580; page 578, 2<sup>nd</sup> col., 2<sup>nd</sup> parag. under The cellular basis of schizophrenia) that do not have the same etiology as Nasu-Hakola disease. Further, while Schmitt et al. indicate that there appears to be a pathological relationship between a decrease in myelination and oligodendrocyte dysfunction and schizophrenia (Schmitt et al., abstract), Schmitt et al. do not indicate that these patients have schizophrenia associated with disruption in DAP12 gene function, independent of Nasu-Hakola disease, such that the claims are enabled for their scope.

Thus, the claims remain rejected.

Examiner's suggestion: Rather than have the neuropsychiatric disorders be associated with disruption in DAP12 gene function, the neuropsychiatric disorders could be associated with Nasu-Hakola disease.

***Conclusion***

No claims allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joanne Hama, Ph.D. whose telephone number is 571-272-2911. The examiner can normally be reached Monday through Thursday and alternate Fridays from 9:00-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

JH

ANNE M. WEHBE PH.D.  
PRIMARY EXAMINER

